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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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7

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/325.963

Applicant(s)

ALBRECHT ET AL.

Examiner

Leanna Roche

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-17 and 25-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 and 18-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-17 and 25-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's election with traverse of Group II, Claims 13-17 and 25-33 in Paper No. 6 is acknowledged. The traversal is on the grounds that the inventions are so interrelated as to not cause a serious burden on the Examiner and examination of all groups would prevent duplication of work by the Office. Additionally, it is argued that there is a financial burden on the Applicant to prosecute the applications necessary to have all the groups examined. This is not found persuasive because the feature of novelty in each of the inventions is not related. While the inventions of Groups I and II are all directed to breathable foams, the inventive portion of the inventions are different in each case. This creates a burden for the Examiner by causing the Examiner to examine in two different directions within one application. With respect to the financial burden, this is not a consideration for a restriction requirement, but a decision for the Applicant. Therefore, the restriction requirement is still deemed proper and is therefore made **FINAL**.

The amendment to Claim 32 has been entered and is found sufficient to overcome the rejection under 35 U.S.C. 112, second paragraph, with regards to the lack of antecedent basis for the limitation "an A layer."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-17, 25-27, 29, 32 and 33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Volke (USPN 4743499).

Volke is directed to a wound dressing comprised of a flexible, completely open-cell polymer foam core such as flexible polyurethane foam. This reads on Applicant's thermoplastic, amorphous foam layer. Because pores are three-dimensional, they are inherently perpendicular to at least one side of the sheet of foam in which they are a part. The completely open-cell foam core of Volke would inherently have pores open at surfaces 16 and 17 and extending into the depth of the foam body forming a perpendicular relationship with surfaces 16 and 17 of the foam (Figure 2). The foam core of Volke is sandwiched between two polymeric film layers. The polymeric film layers are unfoamed. Volke describes the foam core as being a flexible, open-cell, polyurethane foam. The *Polymer Science Dictionary* describes a flexible polyurethane foam as having high resiliency and elasticity (*Polymer Science Dictionary* Second

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Edition by Mark Alger, Chapman & Hall, 1989, pg. 199-200). Resilience is the ability of a strained body to recover its size and shape after deformation. Additionally, Volke explains that the foam core can be repeatedly crushed and it will spring back to its original form. Therefore, the flexible foam of Volke reads on Applicant's foam layer whose porosity may be increased by stretching, but which may recover at least 50% of the increase in porosity upon release from stretching.

Because Volke is comprised of an open-cell foam, it inherently gives the appearance of containing at least one ruptured cell. The polymeric film layers of Volke are heat bonded to the foam core layer. Because Volke is comprised of a foam core layer sandwiched between 2 outer polymeric film layers, Volke reads on the Applicant's claimed ABA structure. Volke also displays a pressure sensitive adhesive laminated to one of the outer polymeric film layers of the composite. This reads on Applicant's claimed pressure sensitive adhesive layer affixed to a major surface of an A layer, and also reads on Applicant's claimed material laminated to at least one A layer.

Volke does not specifically disclose the glass transition temperature of the flexible, completely open-cell polymer foam core. However, it appears that the flexible, open-cell, polyurethane foam layer disclosed by Volke would be substantially identical to the presently claimed thermoplastic, amorphous, foamed polymer of Applicant. Thus, it is believed by the examiner that the flexible, open-cell, polyurethane foam layer disclosed by Volke would inherently possess a glass transition temperature of less than 20°C and would fall within Applicant's claimed range. See *In re Best*, 195 USPQ 433

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footnote 4 (CCPA 1977) as to the providing of this 35 U.S.C. 103 rejection in addition to the rejection made under 35 U.S.C. 102(b).

Claims 13-17 and 25-28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chen (USPN 3972328).

Chen is directed to a surgical bandage comprised of a semi-open cell polymeric foam layer comprised of various thermoplastic elastomer materials such as polyurethane and styrene-butadiene foams. This reads on Applicant's thermoplastic, amorphous foam layer. Because pores are three-dimensional, they are inherently perpendicular to at least one side of the sheet of foam in which they are a part. The semi-open cell foam core of Chen would inherently have pores open at the upper and lower surfaces of foam core 12 and extending into the depth of the foam body forming a perpendicular relationship with the upper and lower surfaces of foam core 12 (Figure 2). The foam layer of Chen is sandwiched between an unfoamed, outer polymeric film coating and a pressure sensitive adhesive composition layer. Because the foam core of Chen is comprised of a flexible, elastomeric material, it will inherently exhibit resilient properties when stretched. Resilience is the ability of a strained body to recover its size and shape after deformation. Therefore, the flexible foam of Volke reads on Applicant's foam layer whose porosity may be increased by stretching, but which may recover at least 50% of the increase in porosity upon release from stretching.

Chen is comprised of an semi-open cell elastomeric foam core having from 30 to 70% ruptured cells. The foam core layer and the polymeric film layer are laminated to one another using a heat bonding technique.

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Chen does not specifically disclose the glass transition temperature of the flexible, completely open-cell polymer foam core. However, it appears that the semi-open cell thermoplastic elastomeric foam core of Chen would be substantially identical to the presently claimed thermoplastic, amorphous, foamed polymer of Applicant. Thus, it is believed by the examiner that the semi-open cell thermoplastic elastomeric foam core of Chen would inherently possess a glass transition temperature of less than 20°C and would fall within Applicant's claimed range. See *In re Best*, 195 USPQ 433 footnote 4 (CCPA 1977) as to the providing of this 35 U.S.C. 103 rejection in addition to the rejection made under 35 U.S.C. 102(b).

Claims 13-17, 25-27 and 31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bello et al. (USPN 5716621).

Bello is directed to an article comprised of a flexible, open-cell, thermoplastic polyurethane foam layer having an upper surface. This reads on Applicant's thermoplastic, amorphous foam layer having at least one major surface. Because pores are three-dimensional, they are inherently perpendicular to at least one side of the sheet of foam in which they are a part. The pores of the foam layer of Bello open at the upper surface and extend into the depth of the foam body forming a perpendicular relationship with the upper surface of the foam (Figures 2A and 2B). The upper surface of the foam layer is bonded to a moisture vapor permeable, liquid impermeable flexible thermoplastic barrier layer. The thermoplastic barrier layer of Bello is unfoamed. Bello describes the foam layer as being a flexible, open-cell, thermoplastic polyurethane

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foam. The *Polymer Science Dictionary* describes a flexible polyurethane foam as having high resiliency and elasticity (*Polymer Science Dictionary* Second Edition by Mark Alger, Chapman & Hall, 1989, pg. 199-200). Resilience is the ability of a strained body to recover its size and shape after deformation. Therefore, a flexible foam reads on Applicant's foam layer whose porosity may be increased by stretching, but which may recover at least 50% of the increase in porosity upon release from stretching.

Bello is comprised of an open-cell foam. Therefore, the foam layer would inherently give the appearance of at least one ruptured cell. The preferred bonding technique between the foam and barrier layers of Bello is flame bonding, which reads on Applicant's melt-bonding technique. The moisture vapor transmission rate of the composite of Bello is at least 500 g/m²/24 hours.

Bello does not specifically disclose the glass transition temperature of the flexible, open-cell, thermoplastic resin foam layer. However, it appears that the flexible, open-cell, thermoplastic polyurethane foam layer disclosed by Bello would be substantially identical to the presently claimed thermoplastic, amorphous, foamed polymer of Applicant. Thus, it is believed by the examiner that the flexible, open-cell, thermoplastic polyurethane foam layer disclosed by Bello would inherently possess a glass transition temperature of less than 20°C and would fall within Applicant's claimed range. See *In re Best*, 195 USPQ 433 footnote 4 (CCPA 1977) as to the providing of this 35 U.S.C. 103 rejection in addition to the rejection made under 35 U.S.C. 102(b).

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Claims 13, 14 and 17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tenneco Chemicals, Inc. (GB 1321489).

Tenneco is directed to the production of a flexible, foamed, cellular sheet material which may be comprised of foamed polyurethane, polyethylene, and polypropylene (Page 1 lines 11-63). This reads on Applicant's claimed thermoplastic, amorphous, foamed polymer layer. Tenneco stretches the flexible, foamed cellular sheet to orient the pores so that they are parallel to the plane of the sheet and then mechanically ruptures the pore walls (Page 2 lines 58-67). This results in pores which run perpendicular to the major surface of the foam layer. Additionally, Tenneco discloses that when the cells are elongated due to stretching, their total surface area is only slightly increased (Page 4 lines 121-130), but that after the pore walls have been ruptured, the flexible, foamed cellular sheet relaxes to its normal unstretched condition (Page 3 lines 67-69).

Tenneco does not specifically disclose the glass transition temperature of their flexible, foamed, cellular sheet material. However, it appears that the flexible, foamed polyurethane, polyethylene, or polypropylene sheet material disclosed by Tenneco would be substantially identical to the presently claimed thermoplastic, amorphous, foamed polymer of Applicant. Thus, it is believed by the examiner that the flexible, foamed polyurethane, polyethylene, or polypropylene sheet material disclosed by Tenneco inherently possesses a glass transition temperature of less than 20°C and would fall within Applicant's claimed range. See *In re Best*, 195 USPQ 433 footnote 4

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(CCPA 1977) as to the providing of this 35 U.S.C. 103 rejection in addition to the rejection made under 35 U.S.C. 102(b).

Claims 13-17 and 25-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volke (USPN 4743499) as applied to claims 13-17, 25-27, 29, 32 and 33 above, and further in view of Chen (USPN 3972328).

Volke discloses a flexible, open-cell amorphous, thermoplastic foam core, but does not disclose a foam layer comprised of a thermoplastic elastomer. Chen, however, is directed to a surgical bandage whose foam core may be comprised of a semi-open cell styrene-butadiene foam which is an amorphous, thermoplastic elastomer. Elastomers display increased elasticity, and therefore have increased cushioning capabilities. It would have been obvious to the skilled artisan at the time the invention was made to combine the teachings of Volke and Chen, motivated by the desire to produce a bandage with a foam core which displays increased cushioning properties.

Neither Volke nor Chen specifically disclose the moisture vapor transmission rate of the polymeric film/foam article. However, Chen does disclose that the polymeric film be somewhat gas permeable. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the moisture vapor transmission rate of the film/foam article, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*in re Ailer*, 105 USPQ 233). In the present case, it would have been obvious to optimize the moisture vapor transmission

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rate, motivated by the desire to aid in the passage of air to the surface of the skin which is covered by the disclosed bandage.

Response to Arguments

Applicant's arguments filed May 17, 2001 have been fully considered but they have not been found persuasive. The 35 U.S.C. 102(b) rejection by Tenneco Chemicals, Inc. (GB 1321489) held in Paper No. 5 was held incomplete by the examiner and has been revised. Applicant's amendments and remarks with regard to the 35 U.S.C. 102(b) rejection by Tenneco Chemicals, Inc. held in Paper No. 5 are not found persuasive in light of the new rejection enclosed herein. Tenneco is directed to the production of a flexible, foamed, cellular sheet material which may be comprised of foamed polyurethane. As shown in Applicant's own specification, page 12, foamed thermoplastic polyurethane all fall within the purview of Applicant's invention. Therefore, the argument that Tenneco does not disclose thermoplastic polymers capable of use in Applicant's invention is not found persuasive.

The rejections under 35 U.S.C. 102(b)/103(a) over McCormack (WO 95/16562) and McCormack et al. (USPN 6111163) and the 35 U.S.C. 103(a) rejection over McCormack (WO 95/16562 or USPN 6111163) in view of Bierenbaum have been withdrawn in view of the fact that these patents were drawn to a polymeric film, not a polymeric foam as claimed by Applicant. The Examiner apologizes for any confusion. However, Applicant's arguments with respect to claims 13-17 and 25-33 are moot in view of the new ground(s) of rejection.

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Contact Information

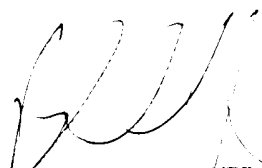
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leanna Roche whose telephone number is 703-308-6549. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Blaine Copenheaver can be reached on 703-308-1261. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Imr
July 29, 2001



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